



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2017-0096]

Nuseed Americas Inc.; Determination of Nonregulated Status of Canola Genetically Engineered For Altered Oil Profile

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that canola designated as event B0050-027, which has been genetically engineered to accumulate the long chain omega-3 fatty acid known as docosahexaenoic acid in seed, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Nuseed Americas Inc. in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: This change in regulatory status will be recognized [Insert date of publication in the Federal Register].

ADDRESSES: You may read the documents referenced in this notice and the comments we received at <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0096> or in our reading

room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents are also available on the APHIS website at [http://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml](http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml) under APHIS Petition 17-236-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: [john.t.turner@aphis.usda.gov](mailto:john.t.turner@aphis.usda.gov). To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: [cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov).

#### SUPPLEMENTARY INFORMATION:

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 17-236-01p) from Nuseed Americas Inc. (Nuseed) of Breckenridge, MN, seeking a determination of

nonregulated status of canola (*Brassica* spp.) designated as event B0050-027, which has been genetically engineered to accumulate the long chain omega-3 fatty acid known as docosahexaenoic acid (DHA) in seed. The Nuseed petition states that information collected during field trials and laboratory analyses indicates that B0050-027 canola is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process<sup>1</sup> for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice<sup>2</sup> published in the *Federal Register* on December 11, 2017 (82 FR 58167-58168, Docket No. APHIS-2017-0096), APHIS announced the availability of the Nuseed petition for public comment. APHIS solicited comments on the petition for 60 days ending on February 9, 2018, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received four comments on the petition. Issues raised during the comment period included concerns regarding product stewardship during production and marketing. These concerns were addressed by Nuseed with supplemental product stewardship data provided to APHIS in support of the petition.

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<sup>1</sup> On March 6, 2012, APHIS published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

<sup>2</sup> To view the notice, the petition, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0096>.

APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS is following Approach 2, where we first solicit written comments from the public on a draft environmental assessment (EA) and a draft plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a *Federal Register* notice. Then, after reviewing and evaluating the comments on the draft EA and the draft PPRA and other information, APHIS revises the draft PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) finding document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the *Federal Register* announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA and a draft PPRA from June 26, 2018, to July 26, 2018.<sup>3</sup> APHIS solicited comments on the draft EA, the draft PPRA, and whether the subject canola is likely to pose a plant pest risk. APHIS received two comments on the petition, both of which supported a decision of nonregulated status for event B0050-027 canola.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and draft PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any

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<sup>3</sup> 83 FR 29742-29743.

potential environmental impacts associated with the determination of nonregulated status of canola designated as event B0050-027. The EA was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of canola designated as event B0050-027).

#### Determination

Based on APHIS' analysis of field and laboratory data submitted by Nuseed, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that canola designated as event B0050-027 is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available

as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22<sup>nd</sup> day of August 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018-18565 Filed: 8/24/2018 8:45 am; Publication Date: 8/27/2018]